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(54) Title: PERITONEAL DIALYSIS FLUID

(57) Abstract

The present invention relates to novel peritoneal dialysis fluids and to the use thereof for performing peritoneal dialysis. The peritoneal dialysis fluid comprises a physiologically acceptable aqueous solution containing physiological acceptable inorganic anions and cations and as an osmotic agent, at least one sugar derivative, said physiological acceptable inorganic anions and cations and said at least one sugar derivative being present in concentrations sufficient for the removal of water and solutes from a patient by peritoneal dialysis, characterised in that the sugar derivative is a compound of formula (I) wherein the or each SG, which may be the same or different, represents a residue of a physiologically acceptable metabolizable sugar, SA represents a residue of aphysiologically acceptable metabolizable sugar alcohol, n is from 1 to 4 and ($\alpha$g) represents a glycoside linkage that is capable of being cleaved by an $\alpha$-glycosidase enzyme.

$$[SG]_{n\ (\alpha g)}[SA] \qquad (I)$$

## Claims

1. A peritoneal dialysis fluid, said fluid comprising a physiologically acceptable aqueous solution containing physiological acceptable inorganic anions and cations and as as osmotic agent, at least one sugar derivative, said physiological acceptable inorganic anions and cations and said at least one sugar derivative being present in concentrations sufficient for the removal of water and solutes from a patients by peritoneal dialysis, characterised in that the sugar derivative is a compound of formula

$$[SG]_n \text{---} [SA]$$

wherein the or each SG, which may be the same or different, represents a residue of a physiologically acceptable metabolizable sugar, SA represents a residue of a physiologically acceptable metabolizable sugar alcohol, n is from 1to 4 and $\text{---}$ represents a glycoside linkage that is capable of being cleaved by an $\alpha$-glycosidase enzyme.

2. A peritoneal dialysis fluid according to Claim 1 wherein the adduct of formula $[SG]_n \text{---} [SA]$ is a hydrogenated oligosaccharide.

3. A peritoneal dialysis fluid according to Claim 1 or Claim 2 wherein n is 1.

4. A peritoneal dialysis fluid according to Claim 3 wherein n is 2.

5. A peritoneal dialysis fluid according to any preceding claim wherein the or each SG represents a glucose residue.

6. A peritoneal dialysis fluid according to any preceding claim wherein SA represents a residue of a sugar alcohol selected from sorbitol, xylitol, ribitol and glycerol

7. A peritoneal dialysis fluid suitable for use in peritoneal dialysis, comprising an aqueous solution of substantially physiological pH, and comprising physiological salts and a sugar derivative as osmotic agent, said fluid being charactised in that the sugar derivative is a hydrogenated di- or tri-saccharide, the concentrations of the components of the fluid being suitable for effecting the removal of water and solutes from a patient by peritoneal dialysis.

8. A peritoneal dialysis fluid according to any preceding claim having a pH in the range from 5.4 to 7.4, preferably from 7.0 to 7.4.

9. A peritoneal dialysis fluid according to any preceding claim containing the following concentrations of the specifed inorganic ions:

| | |
|---|---|
| $Na^+$ | 116-140 mEq/l |
| $Ca^+$ | 0-5 mEq/l |
| $Cl^-$ | 100-144 mEq/l |

10. A peritoneal dialysis fluid according to any preceding claim containing a total of 5 to 40mEq/l of buffering counterions selected from bicarbonate, pyruvate and lactate ions.

11. A peritoneal dialysis fluid according to any preceding claim containing from 1 to 60 g/l of said sugar derivative.

12. A peritoneal dialysis fluid according to Claim 11 containing from 10 to 50 g/l, preferably 35 to 45g/l of said sugar derivative.

13. A peritoneal dialysis fluid according to any preceding claim having an osmolality of 250 to 550 milliOsmols/l, preferably 300 to 500 milliOsmols/l.

14. A peritoneal dialysis fluid according to any preceding claim comprising sugar residues linked by (1-->6) or (1-->4) glycoside linkages.

15. A peritoneal dialysis fluid according to any preceding claim comprising a sugar residue linked to a sugar alcohol residue by a (1–>6) or (1–>4) glycoside linkage.

16. A peritoneal dialysis fluid according to any preceding claim, wherein the sugar derivative is obtainable by chemical modification of a oligosaccharide containing 2 glucosyl units.

17. A peritoneal dialysis fluid according to Claim 16 wherein the chemical modification comprises the transglycosidation of the oligosaccharide.

18. A peritoneal dialysis fluid according to Claim 16 wherein the chemical modification comprises reduction of a terminal glucosyl residue of a disaccharide or trisaccharide.

19. A peritoneal dialysis fluid according to any of Claims 16 to 18 wherein the sugar derivative is obtainable by chemical modification of a oligosaccharide containing 3 glucosyl units.

20. A peritoneal dialysis fluid according to any of Claims 16 to 19 wherein a mixture of sugar derivatives are obtained by chemical modification of a mixture of one or more disaccharides and trisaccharides.

21. A peritoneal dialysis solution according to Claim 16, wherein the sugar derivative is obtainable chemical modification of an oligosaccharide containing between 4 and 9 glycosyl units.

22. A peritoneal dialysis fluid according to any preceding claim comprising an aqueous solution containing a mixture hydrogenated oligosachharides, said hydrogenated oligosachharides having terminal sugar alcohol residues selected from sorbitol, xylitol, ribitol and glycerol.

23. A peritoneal dialysis fluid as claimed in any of Claims 1 to 13 containing Isomalt (Palatinit) as osmotic agent, Isomalt (Palatinit) being a substantially equimolar mixture of alpha-D-glucopyranosido-1,6-sorbitol and alpha-D-glucopyranosido-1,6-mannitol.

24. A peritoneal dialysis fluid according to any preceding claim containing from 125 to 140 mEq/l of sodium, from 90 to 125 mEq/l of chloride, from 1 to 5 mEq/l of calcium, from 0.2 to 5 mEq/l of magnesium, and from 25 to 40 mEq/l of a buffering anion seleceted from lactate, pyruvate and bicarbonate.

25. A peritoneal dialysis fluid according to any preceding claim, having an osmolality of 280 to 455 milliosmols per Liter.

26. A peritoneal dialysis fluid according to any preceding claim comprising essential amino acids to increase the osmolality of the solution, and/or to counterbalance amino acids loss and/or to provide the patient with protein nutrition.

27. A composition for use in preparing a peritoneal dialysis fluid as claimed in any preceding claim by reconstitution by addition of sterile, pyrogen-free water, said composition comprising the specified components in dry form or in the form of an aqueous concentrate.

28. A method of performing peritoneal dialysis which comprises perfusing the peritoneal membrane of a patient with a peritoneal dialysis fluid as defined herein.

29. The use of a compound of formula $[SG]_{n\,(or)}[SA]$ wherein [SG], n and $_{(or)}$ are as defined in any preceding claim, in the manufacture of a peritoneal dialysis fluid.